UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FRANK MICHOLLE, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. OPHTHOTECH CORPORATION, DAVID R. GUYER, and SAMIR PATEL, Defendants.	Civil Action No. 1:17-cv-00210-VSB (Consolidated) ORAL ARGUMENT REQUESTED

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED AMENDED COMPLAINT

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Defendants Ophthotech Corporation ("Ophthotech"), David Guyer and Samir Patel (collectively, "Defendants") submit this memorandum of law in support of their motion to dismiss the Consolidated Amended Complaint for Violations of the Federal Securities Laws, Dkt. 63 (the "Complaint" or "CAC"), in its entirety pursuant to Rules 12(b)(6) and 9(b) of the Federal Rules of Civil Procedure and the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u-4(b).

SUMMARY OF ARGUMENT

The United States Food and Drug Administration ("FDA") has developed a rigorous process for testing the safety and efficacy of new drugs before they can be approved for the market. Drug companies must test new drugs through three phases of progressively larger clinical trials, and must establish first that a drug is safe, second that there is preliminary evidence of the drug's efficacy, and third that the drug is effective in one or more large-scale clinical trials.

One consequence of having such a rigorous testing process is that many drugs that appear promising in early phase clinical trials fail to prove effective in large-scale clinical trials. That is what happened here—Ophthotech's drug Fovista showed promising results in a Phase 2b Trial but did not prove its effectiveness in a larger Phase 3 clinical program. Plaintiff attempts to reverse-engineer claims of securities fraud from this disappointing turn of events. However, Plaintiff fails to plead facts supporting any of the primary elements of such a claim, namely that Defendants (1) made materially false or misleading statements, (2) with scienter, (3) that caused Plaintiff's losses.

Most importantly, there are no well-pleaded allegations of falsity. Plaintiff does not allege that Defendants misrepresented the methodology used for any of the Fovista clinical trials or misstated the results of those trials. Instead, Plaintiff contends that Defendants withheld

material information from the market about the Phase 2b and Phase 3 Trials and criticizes the testing methodologies that Ophthotech used for those trials. However, Plaintiff does not support these contentions with a single confidential witness or internal document, relying instead on hindsight and its own unsourced opinions and conclusions. Indeed, Plaintiff's position ignores Defendants' detailed disclosures and is contradicted by other allegations in the Complaint and the documents incorporated therein by reference. Furthermore, Plaintiff's assertions that Defendants should not have characterized the Phase 2b results favorably because the results were allegedly "skewed" by differences in baselines lesion size and visual acuity between the treatment arms and that Defendants should have characterized the Phase 3 Trials as unlikely to succeed because the eligibility criteria may have resulted in the inclusion of patients who had been excluded from the Phase 2b Trial both fly in the face of the fundamental securities law principle that an issuer that accurately discloses facts has no duty to cast them in a negative light.

The Complaint also fails to allege facts that raise the requisite strong inference of scienter. Plaintiff has not adequately alleged that Defendants had the motive and opportunity to engage in fraud; the Defendants' stock sales were all in line with their stock sales from before the putative class period and were either made pursuant to 10b5-1 trading plans or otherwise explained by the vesting of restricted stock unit awards. And Plaintiff has not adequately alleged that Defendants acted consciously or recklessly because they have not alleged any well-pleaded facts suggesting that Defendants knew or had access to any information inconsistent with their public statements.

Finally, Plaintiff's claims fail because the Complaint does not allege loss causation. The "corrective disclosure" here—the Company's announcement that the Phase 3 Trials had been unsuccessful—necessarily could not have revealed anything new about the results of the separate

Phase 2b Trial. Moreover, as to the Phase 3 Trials, Plaintiff fails to plead any connection between the matter alleged to have been misrepresented—the inclusion criteria for the trials—and the ultimate failure of the trials.

For these and other reasons set out below, this Court should dismiss Plaintiff's claims with prejudice.

BACKGROUND[1]

A. The Parties

Defendant Ophthotech Corporation ("Ophthotech" or the "Company") is a biopharmaceutical company based in Manhattan. During the putative class period, which spans from March 2, 2015 through December 12, 2016, CAC ¶ 1, the Company specialized in developing treatments for an eye condition known as age-related macular degeneration ("AMD"). CAC ¶ 2. During that period, Samir Patel served as the Company's President and Vice Chairman of the Board of Directors, *id.* ¶ 21, and David Guyer served as the Company's Chief Executive Officer ("CEO") and Chairman of the Board of Directors, *id.* ¶ 20.

B. Wet AMD and Fovista

Throughout the putative class period, Ophthotech's most advanced product candidate was Fovista, an anti-platelet derived growth factor ("anti-PDGF") agent, which was under investigation for the treatment of a type of AMD known as wet AMD. CAC ¶ 2. Wet AMD is a disorder of the central portion of the retina, which is responsible for central vision and color perception. *Id.* Wet AMD occurs when abnormal blood vessels (known as choroidal neovascularization, or "CNV") form and invade the retina. *Id.* ¶ 29. These abnormal blood

[1] Solely for purposes of this motion to dismiss, Defendants cite to the allegations in the Complaint, but Defendants do not concede the truth of any such allegations and specifically reserve their rights to contest the truth and accuracy of any allegations in the Complaint. Defendants also reference various SEC filings and public statements, which are relied upon or referenced by Plaintiff in the Complaint.

vessels may bleed and leak fluid into the macula. *Id.* Areas of these abnormal blood vessels and altered tissue in the eyes of patients with wet AMD are referred to as lesions. *Id.* ¶ 5 n.2. These lesions cause wet AMD patients to experience symptoms such as blurred vision and blind spots in their visual field. *Id.* ¶ 2.

Fovista was designed to treat wet AMD by blocking proteins that bind to cells on the *outer* lining of the abnormal blood vessels. *Id.* ¶ 3. The Company's intention was for Fovista to be administered in combination with anti-vascular endothelial growth factor ("anti-VEGF") agents, which represent the current standard of care for the treatment of wet AMD. *Id.* Because anti-VEGF agents block proteins that bind to cells on the *inner* lining of the abnormal blood vessels, Ophthotech believed that use of the two treatments *in combination* would be more effective at treating wet AMD than the use of anti-VEGF agents alone. *Id.*

C. Fluorescein-Based Classifications for Wet AMD Lesions: Classic and Occult

Wet AMD lesions have traditionally been divided into subtypes based on whether the lesions are well-defined using an imaging technique called fluorescein angiography ("FA"), or whether they are poorly defined using FA. Ex. 1 (2014 Form 10-K) at 12.[2] Lesions that are well-defined using FA are referred to as "classic" lesions.[3] CAC ¶ 54. Classic lesions are

[2] This Court may consider the Company's 2014 Form 10-K, which is incorporated into the Complaint by reference. CAC ¶ 61; *see ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007) (holding that the court may consider on a motion to dismiss "any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit"). References to "Ex." are to exhibits annexed to the Declaration of Jeremy T. Adler, filed contemporaneously with this Memorandum.

[3] This Court may take judicial notice of the fact that the classic and occult classifications are based on angiographic patterns shown on FA scans after fluorescein dye is injected into a patient, as opposed to structural qualities of the lesions themselves. *See Effie Film, LLC v. Pomerance*, 909 F. Supp. 2d 273, 299 (S.D.N.Y. 2012) ("Courts may take judicial notice of historical facts revealed in authoritative writings when there is no dispute about the authenticity of the materials and judicial notice is limited to factual matters that are incontrovertible." (quoting Weinstein's Federal Evidence, § 201.12[5] at 201-44)). Numerous scientific articles concerning CNV lesions define classic and occult lesions in this manner. *See, e.g.*, Ex. 2 (*Do We Need a New Classification for Choroidal Neovascularization*), at 1333-34; Ex. 3 (*Linking OCT*) at 483. These definitions are incontrovertible, and Plaintiff does not allege that these terms should be defined differently.

typically located above the retinal pigment epithelium ("RPE") layer of the retina. *Id.* Lesions that are poorly defined using FA are referred to as "occult" lesions. Occult lesions are typically located below the RPE layer of the retina. *Id.* Lesions may present as purely classic (where 100% of the CNV is composed of the classic component), predominantly classic (where more than 50% of the CNV is composed of the classic component), minimally classic (where less than 50% of the CNV is composed of the classic component), or pure occult (where 100% of the CNV is composed of the occult component). *Id.*

Although occult lesions are "typically" located below the RPE, CAC ¶ 54, lesions can also be located above the RPE and still be poorly defined on FA because of the limitations associated with FA technology. *Id.* ¶ 57 n.8 ("SD-OCT allows for a more precise assessment of anatomical differences between subtypes of CNV lesions [than FA], *especially with respect to whether neovascularization is located above or below the RPE layer*." (emphasis added)). The Company disclosed the limitations associated with FA in its 2014 Form 10-K, stating that "[FA]'s accuracy in subtype detection can be inconsistent" because "[FA] is limited in detecting the location and position of the abnormal blood vessels relative to the RPE due to the variability and subjectivity inherent in the reading of the [FA]." Ex. 1 (2014 Form 10-K) at 13. In other words, the Company viewed FA-based classifications of classic and occult (which are based on how well-defined the lesions appear using FA) as useful but imperfect proxies for whether wet AMD lesions are located above or below the RPE.

D. The Process for Testing and Approving New Drugs

At all relevant times, Fovista was a drug that was in development but that the FDA had not approved for use. Before a pharmaceutical company can seek approval from the FDA for a new drug, it must conduct three phases of clinical trials of progressively larger size. *See* 21 C.F.R. § 312.21. Phase 1 trials, which usually involve only 20 to 80 subjects, test the drug's

safety and side effects at different doses. *Id.* at § 312.21(a). Phase 2 trials, which typically use a limited patient population of no more than several hundred subjects, are designed to gather additional evidence of a drug's side effects and risks as well as preliminary evidence of its effectiveness. *Id.* at § 312.21(b). If a phase 2 trial provides such preliminary evidence of effectiveness, a company is permitted to perform a phase 3 trial. *Id.* at § 312.21(c). Phase 3 trials, which usually include several hundred to several thousand subjects, test whether the preliminary findings regarding a drug's effectiveness and safety are borne out in an expanded patient population. *Id.*

E. The Phase 2b Trial of Fovista

In or around June 2012, Ophthotech completed its Phase 2b clinical trial of Fovista administered in combination with Lucentis ("Fovista combination therapy") for the treatment of wet AMD. CAC ¶ 4. The study's primary objective was to evaluate the effectiveness of different doses of Fovista combination therapy compared to the administration of Lucentis alone ("Lucentis monotherapy" or "Lucentis-only"). *Id.* ¶ 34. The study's primary efficacy endpoint was improvement in best corrected visual acuity over 24 weeks. *Id.*

In order to select patients for clinical trials, companies use pre-determined inclusion and exclusion criteria. For the Phase 2b Trial, Ophthotech chose to exclude patients with pure occult lesions as assessed by FA. *Id.* ¶ 6; *see also* Ex. 4 (Phase 2b Study) at 225 (requiring lesions with "a classic component [i.e., predominantly classic or minimally classic] on fluorescein angiography").[4] The Company explained to investors in its 2014 Form 10-K that it was excluding such patients because "it would be difficult to adequately observe and measure the changes in the [CNV] morphology using the imaging techniques that were generally available at

[4] The published Phase 2b study is incorporated into the Complaint by reference. CAC ¶¶ 117, 119.

most enrolling sites at the time [Ophthotech] initiated [the] Phase 2b clinical trial." Ex. 1 (2014 Form 10-K), at 24.

On June 13, 2012, Ophthotech issued a press release announcing that the Phase 2b Trial of Fovista showed Fovista 1.5 mg combination therapy demonstrated "superior efficacy over Lucentis . . . monotherapy," and that the results were statistically significant. CAC ¶ 36.

On March 2, 2015, the first day of the putative class period, Ophthotech filed its 2014 annual report on Form 10-K. The Form 10-K disclosed additional detail about the design and results of the Phase 2b Trial. Ex. 1 (2014 Form 10-K) at 23-37. Among other things, the Form 10-K disclosed that the various testing groups in the Phase 2b Trial had different mean lesion sizes at baseline (i.e., at the time the patients entered the trial). It stated that Ophthotech had randomly assigned the 449 patients to the three treatment groups (*i.e.*, the 0.3 mg Fovista combination therapy group, the 1.5 mg Fovista combination therapy group, and the Lucentis monotherapy group) and that the resulting "Lucentis monotherapy group had a greater proportion of patients with large [lesion sizes] compared to the group treated with a combination of 1.5 mg of Fovista and Lucentis." *Id.* at 23, 29.[5]

On October 31, 2016, Ophthotech announced the publication of the Phase 2b Trial in *Ophthalmology*, the Journal of the American Academy of Ophthalmology. CAC ¶ 117. The article reported that the group that received 1.5 mg Fovista combination therapy had an average improvement in visual acuity that was 62% better than the group that received Lucentis monotherapy—a statistically significant difference. Ex. 4 (Phase 2b Study) at 227, 230.

[5] The variation in lesion size between the different groups was the result of the randomization process, which, as stated above, the Company disclosed.

The article also reported several pieces of information concerning the lesion sizes for the participants in the various study groups. First, it reported that the eligibility criteria required patients to have a "total neovascular lesion area . . . of 5 disc areas (DAs) or less," and that patients who met the inclusion criteria were randomized into the treatment groups and control group. *Id.* at 225. Second, it reported that the mean total lesion size for the resulting 1.5 mg Fovista combination therapy group was 1.5 disc areas, and that the mean total lesion size for the resulting Lucentis-only group was 1.8 disc areas. *Id.* at 227. Third, it reported that "[t]he relative treatment benefit in the [Fovista] combination therapy arm was evident regardless of baseline [visual acuity] [or] lesion size . . . ." *Id.* at 230. A bar graph illustrated that when patients were divided into quartiles based on baseline lesion size, the 1.5 mg combination therapy was more effective than Lucentis monotherapy in each subgroup. *Id.* at 228. Similarly, a separate bar graph illustrated that when patients were divided into three groups reflecting high, medium, and low baseline visual acuity, the 1.5 mg combination therapy was more effective than Lucentis monotherapy in each subgroup. *Id.*

F. Advances in Retinal Imaging Technology Between Phase 2b and Phase 3 Studies

Between the time when the Company initiated enrollment in the Phase 2b Trial and the time when it initiated enrollment in the first two Phase 3 Trials in August 2013, there were considerable advances in retinal imaging technology, whereby a technique called spectral domain optical coherence tomography ("SD-OCT") replaced FA as the standard imaging technology for assessing the retina of wet AMD patients. CAC ¶ 57; *see also* Ex. 5 (2015 10-K) at 22, 36. Unlike FA, which uses fluorescein dye to view CNV lesions, SD-OCT uses light reflections to build high-resolution cross-sectional images of the retina that "permit[] enhanced

resolution of the space under the retina and at the RPE level" where the CNV associated with AMD is present. CAC ¶ 57 n.8.

Because SD-OCT does not use fluorescein, it is unable to classify lesions using the FA-based classifications of "classic" and "occult." *Supra* at 4-5 and n.3.[6] However, "SD-OCT allows for a more precise assessment of anatomical differences between subtypes of CNV lesions, *especially with respect to whether neovascularization is located above or below the RPE layer*." CAC ¶ 57 n.8 (emphasis added). Lesions located above the RPE show up on SD-OCT scans as subretinal hyper-reflective material (also referred to as "subretinal highly reflective material" or "SHRM"). SHRM is defined in the medical literature as "mixed moderately to highly reflective material *at or above the RPE layer* and extending upward toward the retina, but not within the neurosensory retina." Ex. 3 (*Linking OTC*) at 485 (emphasis added).[7]

G. Phase 3 Trials

On August 29, 2013, Ophthotech launched its Phase 3 clinical program (consisting of three separate but related trials) to evaluate the safety and efficacy of Fovista administered in combination with anti-VEGF drugs, with the goal of securing approval of Fovista by the FDA and other regulatory agencies. CAC ¶ 43. In many respects, the Phase 3 Trials were designed to be similar to the Phase 2b Trial. As the Company disclosed in its 2014 Form 10-K, the first two Phase 3 Trials would, like the Phase 2b Trial, compare Fovista combination therapy to Lucentis monotherapy, while a third trial would evaluate Fovista in combination with either of two other

[6] Plaintiff alleges that SD-OCT is "capable of detecting lesion characteristics *associated* with classic and occult subtypes," CAC ¶ 57 (emphasis added), but does not allege that SD-OCT is capable of actually identifying classic and occult lesions. Plaintiff does not even identify which characteristics are identifiable using SD-OCT or allege facts concerning the degree to which such characteristics are correlated with classic and occult lesions.

[7] Despite the importance of SHRM to Plaintiff's allegations, the Complaint does not define SHRM. This Court may take judicial notice of the definition of SHRM, as it is also contained in authoritative scientific literature and is incontrovertible. *See supra* note 3.

anti-VEGF drugs to monotherapy with those anti-VEGF drugs. CAC ¶ 44; Ex. 1 (2014 Form 10-K) at 36. Like the Phase 2b Trial, the Phase 3 Trials' primary endpoint measurement was visual acuity. CAC ¶ 45.

Although in many respects, the design of the Phase 3 Trials was identical to the design of the Phase 2b Trial, because of the shift discussed above in what was considered standard imaging technology for patients with wet AMD, the Company chose to switch from using FA to identify patients who met the inclusion criteria in the Phases 1 and 2b Trials to using SD-OCT to identify patients who met the inclusion criteria in the Phase 3 Trials. The Company fully disclosed this change. CAC ¶ 57; *see also* Ex. 1 (2014 Form 10-K) at 81 ("Our Phase 3 clinical program enrolls patients based on a specific definition of the presence of neovascularization with certain characteristics using the commonly employed modality of spectral domain optical coherence tomography, or SD-OCT."); Ex. 5 (2015 Form 10-K) at 36 ("Since the most commonly employed modality for imaging, diagnosing and managing neovascular AMD is currently SD-OCT, we have modified the methodology to determine the patient's eligibility to include SD-OCT criteria.").[8]

As a result of the shift from using FA to SD-OCT for the Phase 3 Trials, the Company also switched from excluding patients with pure occult lesions (which cannot be identified using SD-OCT) to excluding patients whose lesions did not appear to have SHRM (which can). As discussed *supra* at 5, the "classic" vs. "occult" fluorescence-based classifications serve as a proxy for determining whether a lesion is located above or below the RPE, which is exactly what the presence or absence of SHRM on an SD-OCT scan is intended to show.

[8] Plaintiff incorporated the Company's 2015 Form 10-K into the Complaint by reference. CAC ¶ 98.

The Company explained the ways that the Phase 3 inclusion and exclusion criteria were both similar to and different from the Phase 1 and 2b criteria in its 2014 Form 10-K. The Form 10-K informed investors that Ophthotech "modified the methodology used to determine a patient's eligibility under certain of the inclusion and exclusion criteria for [its] Phase 3 clinical trials as compared to [its] Phase 2b clinical trial," but that it "made no *meaningful* changes to the inclusion and exclusion criteria in these Phase 3 clinical trials from those we used in [the] Phase 2b clinical trial." Ex. 1 (2014 Form 10-K) at 36 (emphasis added). It then provided additional detail about what the Company was changing and what it was not. It explained that the Company was changing from using FA to SD-OCT to identify patients who meet the inclusion criteria, stating that "at the time of enrollment . . . SD-OCT will be used to assess the characteristics of abnormal new vessels, which historically, using fluorescein angiography, have been associated with the subtype occult neovascularization." *Id.* at 37.

The Company went on to explain that SD-OCT is a more accurate method for identifying patients with lesions below the RPE than FA. It explained that "fluorescein angiography's accuracy in subtype detection can be inconsistent," and that "the use of fluorescein angiography is limited in detecting the location and position of the abnormal blood vessels relative to the RPE." *Id.* at 13. By comparison, it stated that SD-OCT images "allow for a more precise analysis of anatomical differences between various angiographic subtypes of CNV lesions . . . , especially with respect to the location of the abnormal new vessels relative to the RPE." *Id.*

Throughout the putative class period, Defendants made additional disclosures about the Phase 3 methodology and inclusion criteria. For example, on a May 11, 2015 earnings call,[9] Dr. Patel explained that the Company was selecting patients for the Phase 3 Trials by looking for the

[9] The transcript of the May 11, 2015 earnings call is incorporated into the Complaint by reference. CAC ¶ 70.

presence of SHRM on SD-OCT, not "classic" presentation by FA. Ex. 6 (May 11, 2015 Conf. Call Tr.) at 5-6. And at an investor day conference on December 3, 2015,[10] Dr. Patel explained the change to the use of SD-OCT to identify patients who met the inclusion criteria for the Phase 3 Trials. At that conference, he said:

> Just for clarification, though, from our perspective . . . fluorescein angiogram . . . was the modality to determine the presence or absence of classic, which in essence, *tries to be a proxy for the presence of neovascularization lying above the retinal pigment epithelium*. Personally, nobody does fluoresceins except for, probably, at the beginning. This day and age, it's all about OCT to image the retina and not the fluorescein. And . . . because [OCT is] an imaging modality that looks at reflectivity, you're looking at the neovascular complex rather than flow and permeability from the dye. *The component of choroidal neovascularization is hence looked at by this reflectivity and the component that's located above the retinal pigment epithelium and the neurosensory retin[a is] by definition, SHRM*.

Ex. 7 (Dec. 3, 2015 Investor Day Tr.) at 28 (emphasis added). In other words, the fluorescein classifications of classic and occult are a proxy for whether a lesion is located above or below the RPE, whereas the presence of SHRM on OCT is a more direct representation of a lesion located above the RPE.

H. Plaintiff's Claims

Plaintiff commenced this action on January 11, 2017 and filed the Consolidated Amended Complaint on June 4, 2018. The putative class period begins on March 2, 2015 (when the Company filed its 2014 Form 10-K that highlighted the results of the Phase 2b Trial and described the ongoing Phase 3 Trials) and ends on December 12, 2016 (the day that the Company disclosed that the Phase 3 Trials observed no benefit from the addition of Fovista to a monthly Lucentis regimen). CAC ¶ 151.

[10] The transcript of the December 3, 2015 investor day conference is incorporated into the Complaint by reference. CAC ¶ 84.

Plaintiff alleges that Defendants made materially false or misleading statements by describing the positive results of the Phase 2b Trial without stating that those results were "skewed" by the differences in baseline lesion size between the 1.5 mg Fovista combination therapy group and the Lucentis monotherapy group, and by discussing the Phase 3 methodology without disclosing that the Company had excluded patients with pure occult lesions from the Phase 2b Trial but potentially included them in the Phase 3 Trials, thereby allegedly diminishing the chances of success in the Phase 3 Trials.

ARGUMENT

I. THE COMPLAINT FAILS TO STATE A CLAIM UNDER SECTIONS 10(B) AND RULE 10B-5

To survive a motion under Rule 12(b)(6), a complaint must "contain sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Plausibility is present "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* While "all allegations contained in the complaint are assumed to be true, this tenet is 'inapplicable to legal conclusions.'" *In re Pretium Res. Inc. Sec. Litig.*, 256 F. Supp. 3d 459, 470 (S.D.N.Y. 2017) (Broderick, J.) (internal citation omitted). Dismissal is appropriate where the plaintiff fails "to raise a right to relief above the speculative level." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007).

"To state a claim under § 10(b) and Rule 10b-5, [the] plaintiff[] must allege that [a defendant] '(1) made misstatements or omissions of material fact; (2) with scienter; (3) in connection with the purchase or sale of securities; (4) upon which [the] plaintiff[] relied; and (5) that [the] plaintiff['s] reliance was the proximate cause of [his] injury.'" *Lattanzio v. Deloitte*

& Touche LLP, 476 F.3d 147, 153 (2d Cir. 2007). An omission or misstatement is material when there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available" to the market. *IBEW Local Union No. 58 Pension Tr. Fund & Annuity Fund v. Royal Bank of Scot. Grp., P.L.C.*, 783 F.3d 383, 390 (2d Cir. 2015).

Federal Rule of Civil Procedure 9(b) requires that allegations of fraud be pled with particularity. To satisfy this requirement, the complaint must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Novak v. Kasaks*, 216 F.3d 300, 306 (2d Cir. 2000).

Additionally, the Private Securities Litigation Reform Act of 1995 (the "PSLRA") requires a private litigant to "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). The PSLRA also imposes a heightened scienter requirement, demanding that the plaintiff "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id.* § 78u-4(b)(2). Allegations premised on "distorted inferences and speculations" do not suffice. *ATSI Commc'ns*, 493 F.3d at 104.

As shown below, the Complaint does not state a violation of Section 10(b) or Rule 10b-5 claim because it does not adequately allege (1) a materially false or misleading statement, (2) scienter, or (3) loss causation.

A. The Complaint Does Not Adequately Allege Any False or Misleading Statement Regarding the Phase 2b or Phase 3 Trials

The Complaint alleges that Defendants made two types of false or misleading statements. *First*, it alleges that statements touting the results of the Phase 2b Trial[11] were misleading because Defendants allegedly knew but failed to disclose that the results of the study were "skewed by the fact that patients in the Lucentis-only group had larger lesions and poorer vision at baseline than patients in the Fovista combination group." *See, e.g.*, CAC ¶ 62. *Second*, it alleges that statements describing the Phase 3 inclusion and exclusion criteria[12] were misleading because Defendants knew but failed to disclose that the Company had "made [a] meaningful change[] to the inclusion and exclusion criteria in the[] Phase 3 clinical trials from those [] used in [the] Phase 2b clinical trial" that made success of the trial less likely. *See, e.g.*, CAC ¶ 64.[13] As explained below, Plaintiff has not adequately alleged that any of these statements was false or misleading. On the contrary, Defendants disclosed the differences in baseline lesion size and the changes to the Phase 3 methodology, Plaintiff points to no well-pleaded contrary facts, and Defendants had no duty to characterize the facts in the way Plaintiff prefers.

[11] These statements include the statements alleged in Paragraphs 61, 67, 68, 72, 73, 75, 76, 80, 84, 86, 88, 92, 96, 98, 106, 111, 113, 117, 119 of the Complaint.

[12] These statements include the statements alleged in Paragraphs 61, 63, 75, 76, 82, 86, 90, 94, 98, 108 and 115 of the Complaint.

[13] The Complaint does not allege that any of Defendants' statements describing its Phase 2b Trial as "the largest Phase II trial ever done in wet AMD" were false or misleading. CAC ¶ 86; *see also* CAC ¶¶ 68, 72-73, 76, 80, 88 (quoting similar statements). Nor does the Complaint allege that statements in a Company press release quoting others as having said that the Phase 2b Trial results were "extraordinary" and a "breakthrough" were actionable misstatements. That is for good reason. Statements of this nature are quintessential non-actionable puffery. *See OptoLum, Inc. v. Cree, Inc.*, 244 F. Supp. 3d 1005, 1011 (D. Ariz. 2017) (statements regarding "'breakthroughs' are 'not specific, not concreate, not measurable, and therefore puffery.'") (citation omitted); *Brodsky v. Yahoo! Inc.*, 592 F. Supp. 2d 1192, 1200 (N.D. Cal. 2008) (statement that company "'did an extraordinary job this quarter'" is puffery); *In re eSpeed, Inc. Sec. Litig.*, 457 F. Supp. 2d 266, 286 (S.D.N.Y. 2006) ("innovative solutions" is puffery).

1. Defendants' Statements About the Phase 2b Results Were Not False or Misleading

Plaintiff does not contend that any of Defendants' factual statements concerning the Phase 2b Trial were false. Instead, Plaintiff alleges that Defendants' various statements describing the positive results of the Phase 2b Trial—namely, the fact that the Fovista combination therapy demonstrated a 62% comparative benefit in mean change in visual acuity over Lucentis monotherapy—were misleading because the statements "failed to disclose that the results of the Phase 2b Trial were not indicative of Fovista's efficacy, since those results were skewed by the fact that patients in the Lucentis-only group had larger lesions and poorer vision at baseline than patients in the Fovista combination [therapy] group." CAC ¶¶ 62, 69, 74, 77, 81, 85, 87, 89, 93, 97, 99, 107, 114, 118. This contention fails for at least three independent reasons. First, Defendants *repeatedly* disclosed differences between the Lucentis-only group and the Fovista combination therapy group. Second, Plaintiff has not adequately alleged that the results of the Phase 2b Trial were skewed by the alleged differences in lesion size and baseline visual acuity. Third, the securities laws do not require companies to depict the results of clinical trials in a negative or pejorative light.

a. Defendants Repeatedly Disclosed Differences Between the Phase 2b Groups

Documents incorporated into the Complaint plainly show that Defendants disclosed the very information about differences between the Phase 2b groups that Plaintiff now alleges they failed to disclose.[14] In fact, on the *very first day* of the putative class period, the Company disclosed in its Form 10-K that the "Lucentis monotherapy group had a greater proportion of

[14] On a motion to dismiss, the court may properly consider "documents incorporated by reference in the complaint . . . [and] document[s] integral to the complaint." *DiFolco v. MSNBC Cable L.L.C.*, 622 F.3d 104, 111 (2d Cir. 2010).

patients with large CNV [lesion] sizes compared to the group treated with a combination of 1.5 mg of Fovista and Lucentis." Ex. 1 (2014 Form 10-K) at 29. Defendants disclosed this information again in their 2015 Form 10-K. Ex. 5 (2015 Form 10-K) at 29.

Defendants disclosed even more information about the differences in lesion sizes between the two groups and the efforts that the study took to control for those differences when they published results of the Phase 2b study in the journal *Ophthalmology* on October 28, 2016. That article disclosed that the mean total lesion size for the Lucentis-only group was 1.8 disc areas and that the mean total lesion size for the 1.5 mg Fovista combination therapy group was 1.5 disc areas. Ex. 4 (Phase 2b Study) at 227. It also explained that the Company had controlled for lesions size and that "[v]isual acuity outcomes favored the 1.5 mg [Fovista] combination therapy group regardless of . . . lesion size." *Id.* at 227-28.

A securities fraud claim cannot be premised on alleged nondisclosure of information that was in fact disclosed. *See, e.g.*, *In re Seadrill Ltd. Sec. Litig.*, 2016 WL 3461311, at *9 (S.D.N.Y. June 20, 2016) ("There can be no omission where the allegedly omitted facts are disclosed.") (citing *Wilson v. Merrill Lynch & Co.*, 671 F.3d 120, 131-32 (2d Cir. 2011)); *In re Pretium Res.*, 256 F. Supp. 3d at 476 (finding statements to be not misleading when "same documents on which the [the complaint] relies for the purported misstatements disclose the information Plaintiffs claim [Defendant] to have omitted"). Similarly, where information is disclosed, an issuer is not required to repeat the disclosure each time it discusses the subject matter. *See In re EDAP TMS S.A. Sec. Litig.*, 2015 WL 5326166, at *11 (S.D.N.Y. Sept. 14, 2015) (holding that defendants were not obligated to reproduce comprehensive list of adverse events every time they discussed treatment's safety profile because information was contained in publicly available reports and additional instances of disclosure would not have altered total mix

of information available to market). As a result, Plaintiff has not adequately alleged that Defendants failed to disclose information about the differences in lesion sizes between the 1.5 mg Fovista combination therapy and Lucentis monotherapy groups of the Phase 2b Trial.

b. Plaintiff Has Not Adequately Alleged That the Results of the Phase 2b Trial Were Skewed By Differences Between the Groups

Plaintiff also has not alleged any well-pleaded facts showing that any differences in baseline lesion size and visual acuity in the Phase 2b groups "skewed" the results of the trial. Instead, the Complaint merely concludes, without any source, that the differences in mean total lesion size between the Fovista combination therapy group and the Lucentis monotherapy group—which the Company disclosed—were "significant because larger lesions tend to be more chronic, severe and difficult to treat." CAC ¶ 51. These perfunctory and unsourced allegations do not meet the requirements of Rule 9(b) or the PSLRA. *See In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 526 (S.D.N.Y. 2015) ("[P]laintiffs 'must do more than say that the statements . . . were false and misleading; they must demonstrate with specificity why and how that is so.'" (citations omitted)), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016).[15]

Plaintiff also ignores that Defendants disclosed that they controlled for the differences in lesion size and visual acuity between the Fovista combination therapy and the Lucentis monotherapy groups and does not plead any facts suggesting that the methodology for doing so

[15] Plaintiff also alleges that Defendants failed to disclose that the Lucentis-only group had "poorer vision . . . at baseline" than patients in the Fovista combination group. However, the Complaint does not allege any well-pleaded facts to support this naked assertion. Instead, it provides nothing more than speculation, stating that "it is likely that patients in the Lucentis-only group, on average, had poorer visual acuity at baseline than patients in the Fovista combination group, since larger lesions correlate with poorer visual acuity." CAC ¶ 52. Unsupported conclusory assertions are insufficient to satisfy the heightened pleading standard of 9(b). *See ATSI Commnc'ns*, 493 F.3d at 99; *Kleinman v. Elan Corp.*, 706 F.3d 145, 154 (2d Cir. 2013) (characterizing the allegation that a control group exhibited an unusual characteristic which allegedly exaggerated a trial's efficacy results as "only [plaintiff's] view" that "[d]efendants are not required to adopt."). However, even if Plaintiff had adequately alleged that patients in the Lucentis-only group had significantly poorer vision, its claims would still fail for the reasons explained herein.

was in any way inadequate. To the extent such a criticism is implicit in Plaintiff's position, it would fail because "the securities laws do not recognize a fraud claim premised on criticism of a drug trial's methodology, so long as the methodology was not misleadingly described to investors." *Abely v. Aeterna Zentaris Inc.*, 2013 WL 2399869, at *6 (S.D.N.Y. May 29, 2013) (citing *Kleinman v. Elan Corp., plc*, 706 F.3d 145 (2d Cir. 2013)); *see also In re Keryx Biopharmaceuticals, Inc., Sec. Litig.*, 2014 WL 585658, at *10 (S.D.N.Y. Feb. 14, 2014) ("[I]in scrutinizing a [false statement or omission] claim, a court does not judge the methodology of a drug trial."); *In re MELA Sci., Inc. Sec. Litig.*, 2012 WL 4466604, at *13-14 (S.D.N.Y. Sept. 19, 2012) (holding that allegations that defendants failed to disclose their use of an "unsound statistical analysis" were insufficient to plead falsity in a 10b-5 claim); *In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 567 (S.D.N.Y. 2011) ("Plaintiffs cannot premise a fraud claim upon a mere disagreement with how [defendants] chose to interpret the results [of a clinical trial].").

c. Defendants Were Not Required to Cast Negative Light on the Results of the Phase 2b Trial

Even if Plaintiff's allegations were well pleaded—which they surely are not—they would still fail because Defendants had no obligation to report the results as "skewed" or to otherwise adopt Plaintiff's preferred language.

"[T]he law is clear that companies need not depict facts in a negative or pejorative light or draw negative inferences to have made adequate disclosures." *Singh v. Schikan*, 106 F. Supp. 3d 439, 448 (S.D.N.Y. 2015) (rejecting allegation that Defendants failed to highlight changes in enrollment criteria and describe potential negative impact of those changes where Defendants detailed each study's design, allowing investors to compare information themselves); *Solow v. Citigroup, Inc.*, 2012 WL 1813277, at *4 (S.D.N.Y. May 18, 2012), *aff'd*, 507 F. App'x 81 (2d Cir. 2013) ("[A defendant] is not obligated to characterize its performance . . . in negative terms

. . . or paint themselves in the most unflattering light possible."). Here, Plaintiff's allegation that Defendants failed to disclose that the results of the Phase 2b study "were not indicative of Fovista's efficacy" and were "skewed" is—given Defendants' ample factual disclosures—nothing more than an inactionable complaint that Defendants put too positive of a spin on the results of the Phase 2b Trial. *See In re Sanofi-Aventis*, 774 F. Supp. 2d at 567 ("Plaintiffs cannot premise a fraud claim upon a mere disagreement with how [defendants] chose to interpret the results [of a clinical trial]."). That Plaintiff might have preferred the Company use different language does not state a fraud claim. *See Solow*, 2012 WL 1813277, at *4.

2. Plaintiff Has Not Adequately Alleged Any Materially False or Misleading Statement Concerning Phase 3 Trial Eligibility Criteria

Plaintiff next alleges that Defendants made false or misleading statements when they characterized the inclusion criteria for the Phase 3 Trials as being substantially similar to the inclusion criteria for the Phase 2b Trial, and when they described specific aspects of the two methodologies, CAC ¶¶ 65, 70, 90, 104. However, Plaintiff's theory of falsity is flawed in three separate respects, each of which is, on its own, fatal to Plaintiff's claims: (1) Defendants fully disclosed the information that Plaintiff alleges they withheld about the Phase 3 inclusion criteria; (2) Plaintiff has not adequately alleged that any of the changes that Defendants made had the effect of making the approximately 40% of patients with lesions characterized as pure occult on FA eligible for the Phase 3 Trial; and (3) even assuming Plaintiff had adequately alleged the inclusion of such patients, Plaintiff has not adequately alleged that the inclusion of patients with pure occult lesions somehow increased the risk that the Phase 3 Trial would be unsuccessful.

a. Plaintiff Has Not Adequately Alleged That Defendants' Statements Concerning Inclusion Criteria Were Materially False or Misleading

Plaintiff's primary allegation concerning the Phase 3 Trials is that Defendants misrepresented that the inclusion criteria were substantially similar to the inclusion criteria for the Phase 2b Trial. CAC ¶¶ 61, 63, 65, 70, 75, 76, 82, 86, 90, 94, 98, 102, 108, 115. According to the Plaintiff, Defendants failed to disclose that the Company "made a significant change to the patient enrollment criteria for the Phase 3 Trials with respect to lesion subtypes." *Id.* ¶¶ 59, 62, 64, 66, 71, 77, 83, 87, 91, 95, 99, 103, 109, 116.

However, Plaintiff acknowledges (either directly or through incorporation by reference) that Defendants made the following disclosures concerning the change from the use of FA to the use of SD-OCT to identify patients who met the inclusion criteria for the Phase 3 Trials either before the start of the putative class period or very early in the putative class period:

- That the Company changed from using FA to determine whether patients met the eligibility criteria in the Phase 1 and 2b Trials to SD-OCT to determine whether patients met the eligibility criteria for the Phase 3 Trials. CAC ¶ 65 ("We believe *the use of SD-OCT to assess choroidal neovascularization at the time of enrollment in our Phase 3 clinical trials* will alleviate some of the variability and inconsistency inherent in using fluorescein angiography." (quoting 2014 Form 10-K) (emphasis added)); *see also id.* ¶ 63 ("[W]e have modified the methodology used to determine a patient's eligibility under certain of the inclusion and exclusion criteria for our Phase 3 clinical trials as compared to our Phase 2b clinical trial." (quoting 2014 Form 10-K)).

- That the Company planned to use SD-OCT to identify lesions that had characteristics *associated with* pure occult lesions, not pure occult lesions themselves. CAC ¶ 65 ("SD-OCT will be used to assess the characteristics of abnormal new vessels, which historically, using fluorescein angiography, have been *associated with* the subtype occult neovascularization." (quoting 2014 Form 10-K) (emphasis added)).

- That the primary "characteristic" associated with occult lesions that the Company would be using SD-OCT to identify was presence of the lesion above the RPE. CAC ¶ 100 ("For our Phase 3 clinical trials, the reading center . . . assess[es] the eligibility of patients based on *the presence of abnormal new blood vessels relative to the RPE* at the time of enrollment."); *see also id.* ¶ 70 ("[SD-OCT can

be used to] determine[] the location of the fluorelier vascularization with respect to the RPE, *which is what you are really trying to do when you look at classic*." (quoting Ex. 6 (May 11, 2015 Conference Call Tr.) at 6)).

- That the Company planned to identify lesions above the RPE by looking for the presence of SHRM on SD-OCT. Ex. 6 (May 11, 2015 Conf. Call Tr.) at 5-6 (in response to a question about whether the Company was selecting patients for inclusion in the Phase 3 Trials by looking for "classic presentation[,] SHRM or both," Dr. Patel responded: "So, it's SHRM by OCT."); *see also* Ex. 5 (2015 Form 10-K) at 94 ("Our Phase 3 clinical program enrolls patients based on a specific definition of the presence of neovascularization with certain characteristics, including the presence of subretinal hyper-reflective material, or SHRM, using the commonly employed modality of spectral domain optical coherence tomography, or SD-OCT.").

The above-referenced disclosures conclusively rebut Plaintiff's allegations that Defendants failed to disclose changes to the inclusion criteria for the Phase 3 Trial. Further, at an investor day conference on December 3, 2015, Dr. Patel explained that the fluorescein classifications of classic and occult are merely "a proxy" for whether a lesion is located above or below the RPE, whereas the presence of SHRM on OCT is a more direct representation of a CNV lesion "located above the [RPE]." Ex. 7 (Dec. 3, 2015 Investor Day Tr.) at 28 (emphasis added).[16] That is *exactly* what Plaintiff incorrectly alleges that Defendants failed to disclose. *See, e.g.*, CAC ¶ 62. In light of these numerous disclosures (all of which are alleged in or incorporated by reference into the Complaint), Plaintiff cannot reasonably contend that Defendants concealed any material information. *See* cases cited *supra* at 17-18.[17]

[16] This portion of the transcript followed shortly after an analyst stated that he "noticed there was a change in the inclusion criteria of the ongoing studies from subfoveal CNV with some classic to active CNV secondary to AMD with the presence of SHRM as someone alluded to earlier" and asked for the panel's thoughts on the clinical significance of the change. *Id.* at 26. There can be little doubt that the information that Plaintiff alleges was withheld from the market was not only disclosed to the market but was understood by the market.

[17] Certain of the challenged statements are also forward-looking statements identified as such in the Company's disclosures, and are therefore protected by the PSLRA safe harbor. 15 U.S.C. § 78u-5e; *In re Sanofi*, 87 F. Supp. 3d at 529.

Unable to allege that Ophthotech failed to disclose any changes made regarding how it identified patients who met the inclusion criteria, Plaintiff focuses on Ophthotech's statements that any change to inclusion criteria was "no[t] meaningful." *See, e.g.*, CAC ¶ 53. Plaintiff claims that requiring the presence of SHRM had the effect of making "the estimated 40% of wet AMD patients with pure occult lesions eligible to participate in the Phase 3 Trials," CAC ¶ 64, and thereby "materially increased the risk that the seemingly favorable results of the Phase 2b Trial would not be replicated in the Phase 3 Trials," CAC ¶ 59. But these allegations not only find no support in any well-pleaded factual allegations in the Complaint, they are also contradicted by other allegations in the Complaint.

For the allegation to be true that using SD-OCT made all 40% of wet AMD patients with pure occult lesions eligible for the Phase 3 Trials, SHRM would have to be present in *all* patients with pure occult lesions. Plaintiff does not, however, allege that SHRM is present in all or even most patients with pure occult lesions. In fact, Plaintiff does not allege any facts that would allow the Court to determine what percentage of pure occult lesions contain SHRM. Instead, Plaintiff merely alleges that "SHRM *can be present* in patients whose lesions have either classic or occult components—including patients with pure occult lesions." CAC ¶ 58. And, Plaintiff does not cite even a single witness or document that supports this claim.

What is more, other allegations in the Complaint demonstrate SHRM is frequently *not* present in pure occult lesions. Plaintiff alleges that occult lesions are "typically located below the RPE layer of the retina," *id.* ¶ 54, meaning that occult lesions "typically" will *not* cause SHRM—which is located at or above the RPE—to be present. To the extent there are exceptional examples of lesions that are characterized as occult using FA but that have SHRM, that is entirely consistent with the Company's disclosures that "[FA] is limited in detecting the

location and position of the abnormal blood vessels relative to the RPE due to the variability and subjectivity inherent in the reading of the [FA]." Ex. 1 (2014 Form 10-K) at 13.

Finally, Plaintiff alleges no facts supporting the conclusion that by changing the inclusion criteria to possibly allow patients with pure occult lesions in the Phase 3 Trials, Defendants materially increased the risk that the trials would fail. CAC ¶ 59. Specifically, Plaintiff provides no well-pleaded factual allegations indicating that Fovista could not treat pure occult lesions as well as lesions with some classic component. Instead, Plaintiff merely alleges that "Defendants knew, or should have known, that the changed enrollment criteria significantly impacted the Phase 3 Trials' prospects for success, because when images of patients' lesions were examined at the end of Ophthotech's phase 1 clinical trial of Fovista, the occult components of the lesions appeared to be unaffected by treatment with Fovista." CAC ¶ 60. However, this allegation is unsourced, and, in fact, the article disclosing the results of the Phase 1 Trial, which is incorporated by reference into the Complaint, CAC ¶ 60, makes no reference to any such finding. *See generally* Ex. 8 (Phase 1 Study); *see also In re Sanofi*, 87 F. Supp. 3d at 526 ("[P]laintiffs 'must . . . demonstrate with specificity why and how [the statements were false or misleading].'") (citation omitted). *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 154 (S.D.N.Y. 2013) (characterizing unsourced criticisms of trial design as merely "[plaintiff's] view" which "Defendants are not required to adopt"). The notion that, with its expertise in the field, Ophthotech would deliberately sabotage its own clinical trial, makes no sense, but that is the logical implication of Plaintiff's position.[18]

[18] With no factual support for its contentions, Plaintiff is left with nothing more than its own inactionable disagreement with the fully-disclosed change in inclusion criteria, *see Abely v. Aeterna Zentaris Inc.*, 2013 WL 2399869, at *6 (S.D.N.Y. May 29, 2013) ("[T]he securities laws do not recognize a fraud claim premised on criticism of a drug trial's methodology . . . ."), or its inactionable preference that Defendants have cast the change in a more negative light, *see supra* at 19-20.

b. Plaintiff Has Not Adequately Alleged That Any of Defendants' Other Statements Concerning the Phase 3 Inclusion Criteria Were Materially False or Misleading

For the same reasons, Plaintiff has not adequately alleged that any of Defendants' other statements concerning the inclusion criteria for the Phase 3 Trial were materially false or misleading.

Plaintiff challenges, on the same grounds, the statement that SD-OCT was a "considerable advancement" over FA in "[t]he process for determining whether or not a wet AMD patient has pure occult" lesions. CAC ¶ 66. But Plaintiff ignores the portion of this disclosure that states: "SD-OCT will be used to assess the characteristics of abnormal new vessels, which historically, using fluorescein angiography, *have been associated with the subtype occult neovascularization*." *Id.* ¶ 65. As explained above, the Company fully disclosed how it intended to use SD-OCT to assess patients for the Phase 3 Trial.

Plaintiff also alleges that Defendants misrepresented that SHRM was "equivalent" to classic lesions, that the use of SD-OCT imaging would result in "better and more accurate" categorization of patients by lesion subtype, that there is "no occult in our pivotal [Phase 3] study," and that "there [is] no reason for us to believe that [the group of patients who meet the Phase 3 selection criteria] constitutes a different group of patients. *See, e.g.*, CAC ¶¶ 70-71, 90-91, 104-05, 115-16. Again, Plaintiff claims that: "SHRM was not 'equivalent' to classic lesions because SHRM may be present in patients whose lesions have either classic or occult components—including patients with pure occult lesions." CAC ¶ 71. However, as explained above, the Complaint does not plead sufficient facts to support this allegation, and in fact concedes that SD-OCT "allows for a more precise assessment of anatomical differences between subtypes of CNV lesions." CAC ¶ 57 n.8. Furthermore, when Dr. Patel stated in response to an analyst question that "there is no occult in our pivotal [Phase 3] study," he explained that asking

how many patients had occult wet AMD didn't make sense because "the definition of occult requires [fluorescein] angiogram [so] when you don't use fluorescein how can [a statement about including occult patients] be made." *Id.* ¶ 104. The statement, when read in context, is completely consistent with the truth of Defendants' disclosures. Finally, when Dr. Patel stated that there is "no reason for us to believe that [the group of patients who meet the Phase 3 selection criteria] constitutes a different group of patients," *id.* ¶ 115, he also explained the ways in which SHRM on SD-OCT (used for Phase 3) was equivalent to classic presentation on FA (used for Phases 1 and 2b). For the reasons explained above, Plaintiff has not adequately alleged that those statements were false or misleading.[19]

B. Plaintiff Fails to Plead Any Facts Giving Rise to an Inference of Scienter, Much Less the Requisite "Strong Inference"

Under the PSLRA, a plaintiff must allege particularized facts giving rise to a "strong inference that the defendant acted with the requisite state of mind." 15 U.S.C. § 78u-4(b)(2). Specifically, a plaintiff must allege either "facts (1) showing the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." *ATSI*, 493 F.3d at 99 (citation omitted). For an inference to be strong it must be "'cogent and *at least as compelling* as any opposing inference one could draw from the facts alleged.'" *Id.* (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007)) (emphasis in original).

Motive entails "concrete benefits that could be realized by one or more of the false statements and wrongful nondisclosures alleged." *Novak v. Kasaks*, 216 F.3d 300, 307 (2d Cir. 2000) (internal citation omitted). Where Plaintiff "fail[s] to establish motive, [he] bear[s] a

[19] Certain challenged statements are also statements of opinion, and are therefore non-actionable. *Tongue v. Sanofi*, 816 F.3d at 211, 213-14

'correspondingly greater' burden in alleging conscious misbehavior or recklessness." *In re Aratana Therapeutics, Inc. Sec. Litig.*, 2018 WL 2943743, at *20 (S.D.N.Y. June 11, 2018). Alleging conscious misbehavior "requires a showing of deliberate illegal behavior," *Gould v. Windstar Commc'ns, Inc.*, 692 F.3d 148, 158 (2d. Cir. 2012), while recklessness requires "conscious recklessness" or "a state of mind approximating actual intent, and not merely a heightened form of negligence," *S. Cherry St., L.L.C. v. Hennessee Grp. L.L.C.*, 573 F.3d 98, 109 (2d Cir. 2009).

Here, Dr. Guyer's and Dr. Patel's stock sales do not support an inference of motive because they were not dramatically out of line with prior trading practices and were made pursuant to 10b5-1 plans. Moreover, Plaintiff provides no well-pleaded factual allegations indicating that they knew or had access to information indicating that (1) the Phase 2b Trial results did not show Fovista's efficacy because of differences in baseline lesion size, or (2) that using SD-OCT to determine eligibility for the Phase 3 Trials would decrease the likelihood of success in the Phase 3 Trials. In the end, the far more compelling inference from the facts pled is that Defendants believed in good faith that the Phase 2b Trial provided evidence of Fovista's efficacy and that the use of SD-OCT consistent with scientific advances did not increase the risk that the Phase 3 Trials would fail.

1. Plaintiff's Motive and Opportunity Allegations Are Insufficient

Plaintiff alleges that Dr. Guyer's and Dr. Patel's stock sales raise a strong inference of scienter, but attempts to support this allegation by merely listing the alleged proceeds from those sales and the alleged percentage of total shares those sales constituted. CAC ¶¶ 143-46. As a matter of law, this does not suffice.

In this Circuit, the "mere fact that insider stock sales occurred does not suffice to establish scienter . . . . Plaintiffs must [further] establish that the sales were 'unusual' or

'suspicious.'" *In re Gildan Activewear, Inc. Sec. Litig.*, 636 F. Supp. 2d 261, 270 (S.D.N.Y. 2009). Stock sales "are unusual [or suspicious] where the trading was in amounts dramatically out of line with prior trading practices and at times calculated to maximize personal benefit form undisclosed inside information." *Id.* When a defendant's trading during the putative class period is consistent with prior trading practices, it does not raise an inference of scienter, even when the number of shares sold in the putative class period is not identical to the number of shares sold before the class period. *See, e.g.*, *In re Glenayre Techs., Inc. Sec. Litig.*, 1998 WL 915907, at *4 (S.D.N.Y. Dec. 30, 1998) (no inference of scienter where "the individual defendants engaged in comparable cumulative sales" before the class period); *In re Silicon Graphics, Inc. Sec. Litig.*, 970 F. Supp. 746, 768 (N.D. Cal. 1997) (selling 7,600 shares during a quarter in the class period, compared to pre-class period sales of 4,800 shares in one quarter and no shares in another quarter, did not raise an inference of scienter).

The Complaint does not contain any allegations about the Individual Defendants' prior trading practices. In fact, the Defendants' SEC filings demonstrate that the Individual Defendants' stock trading during the putative class period was not significantly different from their prior trading.[20] Both before and during the putative class period, Dr. Guyer exercised stock options to acquire shares of common stock at regularly monthly intervals and then sold those newly acquired shares on the same day. *See* App'x A.[21] For instance, between June 2014 and February 2015 (prior to the class period), Dr. Guyer acquired between 13,136 and 15,034 shares

[20] Where, as here, "a complaint alleges only 'incomplete information' concerning insider sales, the court is 'free to consider defendants' SEC filings to fill gaps on motion to dismiss.'" *Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 587 (S.D.N.Y. 2011); *accord. Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 47 (2d Cir. 1991) ("[W]hen a district court decides a motion to dismiss a complaint alleging securities fraud, it may review and consider public disclosure documents required by law to be and which actually have been filed with the SEC.").

[21] For the convenience of the court, Defendants have summarized the information from the Individual Defendants' Forms 4 in Appendices B and C. *See* Fed. R. Evid. 1006 ("The proponent may use a summary, chart, or calculation to prove the content of voluminous writings . . . that cannot be conveniently examined in court.").

of Ophthotech common stock at the start of each month by exercising options that vested, and then sold those shares on the same day (pursuant to a trading plan, *see infra*). *See* App'x A, Rows 8-35, 38-46. As shown in Appendix A, Dr. Guyer continued this practice during the putative class period with relatively minor increases in the amounts sold that corresponded with the vesting of additional stock options awards that were granted in 2014 and 2015.

Dr. Patel's trades during the putative class period also conform to his prior trading patterns and therefore are not unusual or suspicious. In the 12 months before the putative class period, Dr. Patel made sales once each month in amounts ranging from 14,319 to 27,873. *See* App'x B, Table 1. During the putative class period, he made sales each month of between 12,000 and 27,215 shares. *See* App'x B, Table 2.

The Individual Defendants' stock sales are not suspicious for the additional reason that they were all made pursuant to 10b5-1 trading plans or Restricted Stock Unit ("RSU") Agreements. *See generally* App'x A and B. For instance, Dr. Guyer's sales on January 2 and 4, 2016 were automatic sales pursuant to the prespecified terms of Dr. Guyer's RSU Agreement to satisfy the tax withholding obligations incurred in connection with the vesting of awards granted to him under the Company's 2013 Stock Incentive Plan. App'x A, Table 2, Rows 43-48. The same is true of Dr. Patel's sales on November 4, 2015, January 4, 2016, and June 30, 2016. App'x B, Table 2, Rows 41-53, 59-64 and 92-94. The law is clear that such automatic sales to satisfy tax obligations from the vesting of stock are non-suspicious. *See In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 561 (S.D.N.Y. 2004). And the rest of the class period sales were pursuant to 10b5-1 trading plans that were either entered into before the class period or at a time and in a manner that Plaintiff has not adequately alleged was suspicious. *See* App'x A and B. When 10b5-1 trading plans are entered during a class period, the trades made pursuant

to those plans do not support an inference of scienter unless the plaintiff specifically alleges facts indicating that the timing of the plan's creation is itself suspicious. *See In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 584-86 (S.D.N.Y. 2014), *aff'd* 604 F. App'x 62 (2d Cir. 2015); *In re IAC/InterActiveCorp Sec. Litig.*, 478 F. Supp. 2d 574, 604-05 (S.D.N.Y. 2007).

The Complaint makes the conclusory assertion that "Guyer and Patel's trading plans do not provide a defense to their insider sales because Guyer and Patel adopted and/or amended their trading plans at a time when they were in possession of material, non-public information about the Phase 3 Trials' true prospects for success." CAC ¶ 146. A mere conclusion to that effect is insufficient. *In re Aratana Therapeutics*, 2018 WL 2943743, at *20 (rejecting "generalized allegations" that trading plans adopted during the class period were suspect). As in the *Lululemon* case, "the CAC pleads no facts that even remotely suggest that [Defendants] entered into the Plan[s] 'strategically' so as to capitalize on insider knowledge" and does not adequately "allege that [Defendants] had any non-public information about [the alleged] issues" at the time they executed the plans. *In re Lululemon*, 14 F. Supp. 3d at 585. As described *infra* at 31-32, Plaintiff fails specifically to identify any information available to Dr. Guyer and Dr. Patel that would have indicated that the Phase 2b Trial was not indicative of Fovista's efficacy or that the Phase 3 Trial was unlikely to succeed due to the change in eligibility criteria. Under such circumstances, trades made pursuant to 10b5-1 plans are "not suspicious as to timing or amount so as to raise a strong inference of scienter." *Id.* at 586; *In re Aratana Therapeutics*, 2018 WL 2943743, at *20 ("[T]he [complaint] fails to raise any inference that the plans [adopted during the class period] were themselves suspect.").

2. Plaintiff Fails to Allege Conscious Misbehavior or Recklessness

Plaintiff alleges that Defendants "knew, or should have known, that . . . the results of the Phase 2b Trial were . . . skewed by [differences in baseline lesion size]," CAC ¶ 137, that they

"had no reasonable basis to state that 'the same group of patients' was eligible for inclusion in the Phase 3 Trials as in the Phase 2b Trial," *id.* at ¶ 139, and that Defendants were "on notice of [the] risk" that using SHRM "materially increased the risk that the Phase 3 Trials would fail to replicate the seemingly favorable results of the Phase 2b Trial," *id.* ¶ 140. However, Plaintiff does not identify specific, contemporaneous information that shows that Defendants knew, or were reckless in not knowing this information.

a. Lesion Size Allegations

Plaintiff has not plausibly alleged that Defendants knew or had access to information indicating the results of the Phase 2b study were "skewed" and "not indicative of Fovista's efficacy." To be sure, Defendants had access to "the results of the Phase 2b Trial since 2012." CAC ¶ 141. But this allegation only begs the question: What did the results show? In fact, the published results from the Phase 2b Trial demonstrated that "[t]he relative treatment benefit in the [Fovista] combination therapy arm was evident *regardless of baseline [visual acuity] [or] lesion size*." Ex. 4 (Phase 2b Study) at 230 (emphasis added). Furthermore, the same paper contains graphs showing that the 1.5 mg Fovista combination therapy was more effective than Lucentis monotherapy in each of four subgroups divided by lesion size and each of three subgroups divided by visual acuity. Ex. 4 (Phase 2b Study) at 230.

Plaintiff has not alleged any contrary facts, much less any facts or reports showing that Defendants knew or should have known that the published results were false. *See In re Aratana Therapeutics*, 2018 WL 2943743, at *21 ("Absent concrete allegations as to defendants' knowledge, the [complaint] cannot generate a strong inference of scienter."); *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc.*, 531 F.3d 190, 196 (2d Cir. 2008) (allegations that "'defendants had access to contrary facts . . . must specifically identify the reports or statements containing this information.'").

Moreover, several allegations in the Complaint tend to suggest the *absence* of fraudulent intent. *See Tellabs*, 551 U.S. at 314 ("an inference of scienter must be . . . at least as compelling as any opposing inference of nonfraudulent intent."). For instance, after receipt of the Phase 2b results, the Company continued to invest heavily in the Phase 3 Trials. This shows that Defendants genuinely believed the Phase 2b results evinced the drug's efficacy and, accordingly, anticipated positive results in Phase 3. *See* CAC ¶¶ 38-41, Ex. 1 (2014 Form 10-K) at 67 (describing "significant cash outflows" and expectation of continuously increasing expenses associated with the Phase 3 Trials); *In re Aratana Therapeutics*, 2018 WL 2943743, at *21 (continued investment "suggest[s] the *absence* of fraudulent intent"). That the Phase 2b findings were subjected to peer review and approved for publication in a leading medical journal further indicates that Defendants were not reckless in believing that the Phase 2b data was, in fact, indicative of Fovista's efficacy. *See Kleinman v. Elan Corp.*, 706 F.3d 145, 154 (2d Cir. 2013).

b. Eligibility Criteria Allegations

Plaintiff also repeatedly asserts that Defendants "had no reasonable basis to state that 'the same group of patients' was eligible for inclusion in the Phase 3 Trials as in the Phase 2b Trial" because "SHRM can be present in . . . patients with pure occult lesions." CAC ¶ 139. Again, Plaintiff alleges that "defendants had access to contrary facts," but fails to "specifically identify the reports or statements containing the information" or otherwise say what those facts were. *In re Neurotrope Inc. Sec. Litig.*, 2018 WL 2561024, at *8 (S.D.N.Y. June 4, 2018). The Complaint does not identify any contemporaneous source containing information about how often SHRM presents in patents with lesions that could be classified as pure occult using FA, *see supra* at 23, or any information suggesting that the use of SD-OCT instead of FA for the Phase 3 Trials would have significantly and unfavorably altered the patient population, *see supra* at 23-24. Nor could the Complaint possibly allege that Defendants were reckless in believing that the

presence of SHRM is substantially similar to the classic lesion classification when it acknowledges that the "classic" lesions are "typically located above the RPE." CAC ¶ 54; *see also supra* at 5. Indeed, Plaintiffs elsewhere tout the Defendants' knowledge and expertise in the field. *See* CAC ¶ 142. It defies reason that they would have changed the eligibility criteria in a way that would have undermined the Phase 3 Trials' chance of success.

Furthermore, even if the change to SD-OCT permitted some pure occult lesions (as classified when using FA) to be included in the Phase 3 Trial, Plaintiff has not adequately alleged that it would be reckless to hold the view that adopting SD-OCT would not hurt the likelihood of the Phase 3 Trials' success. Plaintiff's only support for this proposition is that the occult components of lesions in Ophthotech's phase 1 clinical trial were allegedly "unaffected by treatment with Fovista." *Id.* ¶ 140. But, as discussed above, Plaintiff does not and cannot identify any such finding in the Phase 1 results paper to support this conclusory assertion, and in fact there is nothing in the paper that says that. *See supra* at 24.

Ultimately, the far more compelling inference is that Defendants believed that assessing eligibility for the Phase 3 Trials through SD-OCT (and its identification of SHRM), rather than through FA (and its identification of classic lesions) would actually improve the Company's ability to distinguish between the various lesion subtypes, not that it would hinder the likelihood of success. That the Plaintiff may disagree in hindsight does not affect the scienter analysis. *See In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 547-48 (S.D.N.Y. 2015) (rejecting as "purely speculative" allegation that Defendants "knew or should have known that they were misleadingly downplaying . . . [the drug's] side effects" absent allegations that "defendants had access to information about [the drug's] side effects that was not made public").

C. The Complaint Does Not Adequately Allege Loss Causation

To plead loss causation, a plaintiff must allege that the statements at issue are the "but-for

cause or cause-in-fact of the losses suffered." *In re Omnicom Grp., Inc. Sec. Litig.*, 597 F.3d 501, 509-10 (2d Cir. 2010). This requires a plaintiff to show "that the market reacted negatively to a corrective disclosure of the fraud." *Id.* at 511. A statement does not qualify as a "corrective disclosure" simply because it announces bad news and is followed by a decline in the company's stock price. *Leykin v. AT&T Corp.*, 423 F. Supp. 2d 229, 244-45 (S.D.N.Y. 2006), *aff'd*, 216 F. App'x 14 (2d Cir. 2007); *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 175 n.4 (2d Cir. 2005) ("[Announcements of negative information] do not amount to a corrective disclosure . . . because they do not reveal to the market the falsity of the prior recommendations."). To qualify as a corrective disclosure, a statement must reveal a prior statement's false or fraudulent nature. *Id.*

Plaintiff alleges only one corrective disclosure, namely, the Company's December 12, 2016 press release announcing the results of the Fovista Phase 3 Lucentis trials and disclosing that "[n]o benefit [was] observed upon [the] addition of Fovista to monthly Lucentis regimen for the treatment of wet [AMD.]" CAC ¶ 121. But Plaintiff does not and could not allege that the press release disclosed anything about the Phase 2b Trial, much less differences in the trial groups with respect to lesion sizes or visual acuity. Instead, the press release discloses new information to the market concerning the unsuccessful results in two of the separate *Phase 3* Trials. Ex. 9 (Dec. 12, 2016 Press Release). That does not establish loss causation. *See Lentell*, 396 F.3d at 175 n.4; *In re Gentiva Sec. Litig.*, 932 F. Supp. 2d 352, 384-85 (E.D.N.Y. 2013) ("[L]oss causation is not adequately pled simply by allegations of a drop in stock price following an announcement of bad news if the news did not disclose the fraud.").

Similarly, nothing in the Complaint suggests that the failure of the Phase 3 Trials to demonstrate efficacy was proximately caused by—or indeed had anything at all to do with—any change to the inclusion criteria for those trials. Accordingly, the press release did not plausibly

reveal to the market that Defendants previously had misrepresented the significance of the change, nor does it reflect the materialization of any incremental risk that Defendants had concealed.[22] That severs any causal connection between the alleged fraud and the loss. *Lentell*, 396 F.3d at 175 n.4 ("These [announcements of negative information] do not amount to a corrective disclosure . . . because they do not reveal to the market the falsity of the prior recommendations."). Accordingly, Plaintiff has not pleaded loss causation.

II. THE COMPLAINT FAILS TO STATE A CLAIM UNDER SECTION 20(a)

In order to plead a "control person" claim under Section 20(a), a plaintiff must plead: (1) a primary violation by the controlled person, (2) control of the primary violator by the controlling person, and (3) that the controlling person was a culpable participant in the alleged fraud in some meaningful sense. *See Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 170 (2d Cir. 2000). Because the complaint fails to plead a primary violation, the Section 20(a) claim must also be dismissed. *See In re Neurotrope*, 2018 WL 2561024, at *9.

CONCLUSION

For the foregoing reasons, the Complaint should be dismissed in its entirety with prejudice.

[22] Defendants in fact provided ample warnings about the risk that the Phase 3 Trials might fail. *See, e.g.*, Ex. 1 (2014 Form 10-K) at 72 ("There remains a significant risk that we will fail to successfully develop Fovista. The results of our Phase 2b clinical trial may not be predictive of the results of our Phase 3 clinical program due, in part to the fact that we have no clinical data on Fovista combination therapy in any clinical trial longer than 24 weeks, [and] that we have modified the methodology used to determine a patient's eligibility under certain of the inclusion and exclusion criteria for our Phase 3 clinical trials as compared to our Phase 2b clinical trial."); *id.* at 1 (identifying statements about the "outcome of our Phase 3 clinical trials of Fovista" as "forward looking statements that involve substantial risks and uncertainties"); *id.* at 68 ("Our ability to commercialize our product candidates, in particular Fovista, will require us to be successful in a range of challenging activities, including[] obtaining favorable results from our Phase 3 clinical program for Fovista . . . . We may never succeed in these activities.").

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Respectfully submitted,

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